



July 2, 2009

Docket No: 03035572  
EA-09-147

License No.:52-25542-01

Juan E. Pérez Monté, M.D.  
Director and Radiation Safety Officer  
Beta Gamma Nuclear Radiology, Inc.  
P.O. Box 7891, PMB 372  
Guaynabo, PR 00970-7891

SUBJECT: NRC INSPECTION REPORT NO. 03035572/2008001 AND INVESTIGATION  
REPORT NO. 1-2008-052

Dear Dr. Pérez Monté:

This refers to the inspection conducted on March 11, 2008, at your Beta Gamma Nuclear Radiology, Inc. (BGNR), Fajardo, Puerto Rico facility. During the inspection the NRC inspector identified a finding involving the failure, on three occasions, to prepare written directives prior to the administration of sodium iodide iodine-131 (I-131) in quantities greater than 30 microcuries, (e.g., diagnostic doses of I-131 in the 3-5 millicuries range for whole body scans) as required by 10 CFR 35.40(a). The three examples of the violation were for procedures performed on September 14, 2005, and February 19 and 26, 2008. On April 8, 2008, the NRC issued BGNR a Notice of Violation (NOV) for this violation, which was classified at Severity Level IV.

In a sworn and notarized May 5, 2008 response to the NOV, BGNR disputed the violation, indicating that BGNR always prepares written directives for sodium iodide I-131 greater than 30 microcuries prior to administration. BGNR further indicated that the written directives for the three examples mentioned in the NOV had been misfiled and later found after the inspection, and BGNR provided copies of the respective written directives. When reviewing the written directives, the NRC staff noted that the written directive for the whole body scan performed on September 14, 2005, was dated September 14, 2008, i.e., three years after the actual administration and more than four months after the date of BGNR's response.

Due to the discrepancy between the information provided during the inspection and the information provided in response to the NOV, and the fact that the provided written directive for the procedure that was performed on September 14, 2005 was inaccurately dated, the NRC's Office of Investigations (OI) initiated an investigation to determine whether BGNR submitted falsified written directives subsequent to receiving the NOV.

Based on the information obtained during the investigation, the NRC concluded that: (1) a BGNR employee apparently willfully submitted a falsified written directive to support its dispute of the April 8, 2008 NOV, contrary to 10 CFR 30.9(a), "Completeness and accuracy of information," which requires that information provided to the Commission by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the licensee shall be complete and accurate in all material respects; (2) a BGNR employee apparently willfully maintained incomplete or inaccurate required written directives, also in

violation of 10 CFR 30.9; and, (3) the violation contained in the NOV dated April 8, 2008 occurred as stated in the Notice. The OI findings are described in detail in the enclosed Factual Summary of the OI Investigation Report No. 1-2008-052.

The apparent violations involving the creation of inaccurate records, as well as the submittal of the inaccurate records to the NRC, are being considered for escalated enforcement action in accordance with the current NRC Enforcement Policy. The NRC Enforcement Policy is included on the NRC's Website at [www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html](http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html). Because the NRC has not made a final determination in this matter, no Notice of Violation is being issued at this time. In addition, please be advised that the number and characterization of apparent violations described herein may change as a result of further NRC review.

Before the NRC makes its enforcement decision, the NRC would like to discuss these apparent violations with BGNR at a Predecisional Enforcement Conference (PEC) at the NRC Region I office. The decision to hold a PEC does not mean that the NRC has determined that violations have occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether violations occurred, information to determine the significance of the violations, information related to the identification of the violations, and information related to any corrective actions taken or planned. The conference will provide an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

Instead of a PEC, BGNR may request Alternative Dispute Resolution (ADR) with the NRC. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties (the NRC and BGNR) agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Additional information concerning the NRC's ADR process can be obtained at [www.nrc.gov/about-nrc/regulatory/enforcement/adr.html](http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html). The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting the parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistic assistance as necessary. Please contact ICR at Cornell University at (877) 733-9415 within **10** days of the date of this letter if you are interested in pursuing resolution of these issues through ADR.

Regardless of whether you choose a PEC or ADR, please be prepared to summarize your corrective actions and discuss your oversight and implementation of a program that ensures the accuracy of information required to be maintained and information submitted to the NRC. Please contact Pamela Henderson at (610) 337-6952 within **10** days of the date of this letter to notify the NRC of your decision to either participate in a PEC or pursue ADR. A PEC or an ADR

session should be held within 30 days of the date of this letter. If a PEC is held, it will be transcribed and will be closed to public observation in accordance with the NRC's Enforcement Policy because the findings are based on an NRC OI Report that has not been publicly disclosed; however, the time and date of the conference will be announced.

If you do not contact us regarding your participation in either a PEC or ADR within the time period specified, and an extension of time has not been granted by the NRC, we will make an enforcement decision based on available information.

No written response regarding the apparent violations is required at this time. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," after completion of enforcement related activities in this matter, a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS) accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,  
**/RA by Daniel S. Collins for/**

John D. Kinneman, Director  
Division of Nuclear Materials Safety

Enclosures:

1. Factual Summary of OI Investigation Report No. 1-2008-052
2. Excerpt from NRC Information Notice 96-28
3. Brochure NUREG/BR-0317

cc:

Commonwealth of Puerto Rico

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\*see previous concurrence

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Factual Summary  
OI Report No. 1-2008-052

The investigation was initiated at Beta Gamma Nuclear Radiology (BGNR) on July 10, 2008, to determine if an Authorized User (AU)/ Radiation Safety Officer (RSO) submitted falsified written directives subsequent to receiving a Notice of Violation (NOV) from the NRC on April 8, 2008. The NOV described a violation for administering radiopharmaceuticals on three occasions without a written directive being prepared and signed prior to administering the treatments.

The violation described in the NOV was identified during an NRC inspection at BGNR on March 11, 2008. The inspector identified BGNR's failure to prepare written directives for the diagnostic use of I-131 in excess of 30 microcuries, contrary to the requirements in 10 CFR 35.40(a). The written directives were not signed or dated at the time the inspector identified the issue. In demonstrating the finding to BGNR, the inspector showed the AU/RSO three example patient files that did not contain properly prepared written directives, because they were not signed and dated prior to administration of the doses. After the NRC issued the Severity Level IV NOV, in April 2008, the NRC conducted a second on-site inspection at BGNR, and identified one written directive from 2005 that included a 2008 signature. Further, on May 5, 2008, in a response to the NOV contesting the finding, the AU/RSO provided a sworn affidavit containing three copies of the signed and dated written directives previously identified by the NRC inspector as incomplete. The submitted directives included signatures and dates, all for the year 2008, even though one of the written directives was from a patient treatment that occurred in 2005.

During OI's interview of the AU/RSO, OI showed him the directive that was dated and signed in 2008 even though the treatment occurred in 2005. The AU/RSO responded to OI that he had not written "2008" but actually wrote, "2005;" that the "5" just looked like an "8," and actually, could even be mistaken for a "6." He denied that he deliberately altered anything to avoid receiving an NOV. He further stated that since the inspection, he had been checking the patient files, and "I could have fix[ed] one or two that may have been missing something." The AU/RSO also claimed that he intended for BGNR to "triple check" all of the patient files to ensure no other errors had been made.

On March 12, 2009, OI attempted to conduct a second interview with the AU/RSO, accompanied by a senior NRC inspector. When questioned about the three documents he had submitted with the affidavit that appeared to have been back-dated, the AU/RSO declined to be formally interviewed, but offered the comment that he was "human and makes mistakes," and was uncertain as to whether or not he backdated anything, but admitted he may have made changes to it after the fact to "show accuracy." Before leaving the site, OI and the senior inspector completed an additional records review, and identified one additional patient file from 2005 that lacked a signed and dated written directive for an administration of I-131 over 30 microcuries.